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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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WASHINGTON, DC 20001-0300

EXAMINER

ROBERT J.

ART UNIT	PAPER NUMBER
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1647

16

DATE MAILED:

04/02/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Advisory ActionApplication No.
08/981,559Applicant(s)
Wallach et al.Examiner
David RomeoGroup Art Unit
1647

THE PERIOD FOR RESPONSE: [check only a) or b)]

- a) ☐ expires _____ months from the mailing date of the final rejection.
- b) ☐ expires either three months from the mailing date of the final rejection, or on the mailing date of this Advisory Action, whichever is later. In no event, however, will the statutory period for the response expire later than six months from the date of the final rejection.

Any extension of time must be obtained by filing a petition under 37 CFR 1.136(a), the proposed response and the appropriate fee. The date on which the response, the petition, and the fee have been filed is the date of the response and also the date for the purposes of determining the period of extension and the corresponding amount of the fee. Any extension fee pursuant to 37 CFR 1.17 will be calculated from the date of the originally set shortened statutory period for response or as set forth in b) above.

- X Appellant's Brief is due two months from the date of the Notice of Appeal filed on 26 Feb 2001 (or within any period for response set forth above, whichever is later). See 37 CFR 1.191(d) and 37 CFR 1.192(a).

Applicant's response to the final rejection, filed on 26 Feb 2001 has been considered with the following effect, but is NOT deemed to place the application in condition for allowance:

- X The proposed amendment(s):

☐ will be entered upon filing of a Notice of Appeal and an Appeal Brief.

X will not be entered because:

- ☒ they raise new issues that would require further consideration and/or search. (See note below).
- ☐ they raise the issue of new matter. (See note below).
- ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal.
- ☐ they present additional claims without cancelling a corresponding number of finally rejected claims.

NOTE: See the Attachment.

☐ Applicant's response has overcome the following rejection(s):

- ☐ Newly proposed or amended claims _____ would be allowable if submitted in a separate, timely filed amendment cancelling the non-allowable claims.
- X The affidavit, exhibit or request for reconsideration has been considered but does NOT place the application in condition for allowance because:
See the Attachment

☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

- X For purposes of Appeal, the status of the claims is as follows (see attached written explanation, if any):

Claims allowed: none

Claims objected to: none

Claims rejected: 29 and 36

The proposed drawing correction filed on _____ has _____ has not been approved by the Examiner.

Note the attached Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

- X Other Claims restricted: 1-28, 30-35

DAVID ROMEO
PRIMARY EXAMINER
ART UNIT 1647

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Attachment to Paper No. 16 (Advisory Action)

1. The proposed amendment(s) will not be entered because they would necessitate claim 29 being newly rejected under 35 U.S.C. § 101 and § 112, first paragraph, for the reasons at page 7, paragraph 10, of the Office action mailed 09/26/2000 (Paper No. 14).

2. The affidavit, exhibit or request for reconsideration has been considered but does NOT place the application in condition for allowance because: Applicant's arguments are directed to the proposed amendments and the proposed amendments have not been entered.

Applicant further argues that "producing" fully complies with the requirement of 35 U.S.C. § 112, second paragraph. Applicants' arguments have been fully considered but they are not persuasive. The claims require "producing a molecule" but, since the claim does not set forth any steps involved in "producing a molecule" it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a process without any active, positive steps delimiting how this process is actually practiced.

Applicant further request clarification of why claim 36 was rejected under 35 U.S.C. § 101 and § 112, first paragraph, and claim 29 was not, and further argue that the Office action mailed 09/26/2000 (Paper No. 14) was improperly made final because claim 36 is dependent from claim 29 and therefore claim 36 contains all the limitations of claim 29 and should have also been rejected under 35 U.S.C. § 101 and § 112, first paragraph. Applicants' arguments have been fully

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considered but they are not persuasive. Claim 36 did not include all the limitations of claim 29 because claim 29 did not set forth any steps in the screening process, and the recitation of "capable of modulating" is not a positive limitation but only requires the ability to so perform and does not constitute a limitation in any patentable sense. Ohta(u9)¹ described a process that encompassed all the claimed method steps. The screening of LPS has utility because LPS is well known to have many biological activities including immunopotential and toxicity. See Ohta, first sentence of paragraph bridging pages 1-2. It would have been improper to simultaneously reject a claim as being anticipated by a prior art process that has utility and at the same time reject the claim for lack of utility and enablement.

Applicant further argues that unlike the Brenner v. Manson case the present case is directed to methods and that a method of hunting should be patentable. Applicants' arguments have been fully considered but they are not persuasive. In the instant case the claims are directed to a method of screening and a method of producing a compound identified by the screening process. However, the biological significance of the screening process, or the binding to and the modulation of the phosphorylation of the intracellular domain of 26 kDa TNF, is unknown. In the absence of a knowledge of the biological significance of the phosphorylation process there is no

¹References cited by the examiner are in an alphanumeric format, such as "a1", wherein the "a" refers to the reference cited on the Notice of References Cited, PTO-892, and the "1" refers to the Paper No. to which the Notice of References Cited, PTO-892, is attached.

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apparent specific and substantial asserted utility or a well established utility for either the screening process or production of the compounds identified by the screening process. Whether or not a particular method of hunting has a specific and substantial asserted utility or a well established utility is highly dependent upon the individual facts situation in each case and, based on the instant record, a specific and substantial asserted utility or a well established utility is absent. Assertions that the process [to which the claimed screening process is directed] "may be involved in the regulation" or represent the "disclosure of a control possibility" are speculative at best, and describe a "wish to know" type of utility, which is not a specific and substantial utility.

As Applicant recognizes, a rejection under § 112, first paragraph, may be maintained on the same basis as a lack of utility rejection under § 101.

3. Applicants' response would have overcome the following rejection(s) if the proposed response had been entered: the rejection of claim(s) under 35 U.S.C. § 112, second paragraph, over the recitation of "capable of modulating"; the rejection of claim(s) 29 under 35 U.S.C. § 112, second paragraph, over the recitation of "directly or indirectly"; the rejection of claim(s) 29, 36 under 35 U.S.C. § 112, second paragraph, over the recitation of "screening", "identification", and "characterization" of a molecule; the rejection of claim(s) 29 under 35 U.S.C. 102(b) as being anticipated by Ohta (u9).

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ANY INQUIRY CONCERNING THIS COMMUNICATION OR EARLIER COMMUNICATIONS FROM THE EXAMINER SHOULD BE DIRECTED TO DAVID S. ROMEO WHOSE TELEPHONE NUMBER IS (703) 305-4050. THE EXAMINER CAN NORMALLY BE REACHED ON MONDAY THROUGH FRIDAY FROM 6:45 A.M. TO 3:15 P.M.

5 IF ATTEMPTS TO REACH THE EXAMINER BY TELEPHONE ARE UNSUCCESSFUL, THE EXAMINER'S SUPERVISOR, GARY KUNZ, CAN BE REACHED ON (703) 308-4623.

OFFICIAL PAPERS FILED BY FAX SHOULD BE DIRECTED TO (703) 308-4242.

FAXED DRAFT OR INFORMAL COMMUNICATIONS SHOULD BE DIRECTED TO THE EXAMINER AT (703) 308-0294.

ANY INQUIRY OF A GENERAL NATURE OR RELATING TO THE STATUS OF THIS APPLICATION OR PROCEEDING SHOULD BE DIRECTED TO THE GROUP RECEPTIONIST WHOSE TELEPHONE NUMBER IS (703) 308-0196.

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DAVID ROMEO
PRIMARY EXAMINER
ART UNIT 1647

MARCH 30, 2001